

March 15, 2001

**MEMORANDUM**

**SUBJECT:** **THIOPHANATE-METHYL.** Revised HED Product Chemistry and Residue Chemistry Chapters of the RED.  
**PC Code: 102001** DP Barcode D272013.

**FROM:** José J. Morales, Ph.D., Chemist  
Reregistration Branch III  
Health Effects Division (7509C)

**THROUGH:** Catherine Eiden, Branch Senior Scientist  
Reregistration Branch III  
Health Effects Division (7509C)

**TO:** Deborah Smegal, Risk Assessor  
Reregistration Branch III  
Health Effects Division (7509C)  
and  
John Leahy, Chemical Review Manager  
Reregistration Branch I  
Special Review and Reregistration Division (7508W)

Attached is the Revised HED Product Chemistry and Residue Chemistry Chapters in support of the thiophanate-methyl Reregistration Eligibility Decision. This revised chapter reflects incorporation of the registrant "error only" comments made to the 6/16/2000 HED Product and Residue Chemistry Chapters of the RED (J. Morales, D230335).

**THIOPHANATE-METHYL**  
**Shaughnessy No. 102001; Case 2680**  
**(HED Nos. 17601; DP Barcode D230335)**

**Reregistration Eligibility Decision**

**February 28, 2000**

**Contract No. 68-D4-0010**

**Submitted to:**  
**U.S. Environmental Protection Agency**  
**Arlington, VA**

**Submitted by:**  
**Dynamac Corporation**  
**1910 Sedwick Road**  
**Building 100, Suite B**  
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# THIOPHANATE-METHYL

## REREGISTRATION ELIGIBILITY DECISION:

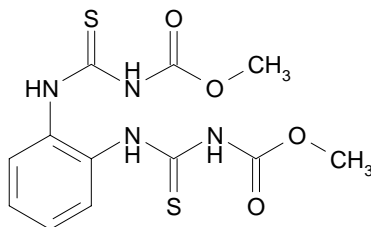
### PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 102001; Case No. 2680

(HED No. 17601; DP Barcode D230335)

### DESCRIPTION OF CHEMICAL

Thiophanate-methyl [dimethyl [(1,2-phenylene)bis(iminocarbonothioyl)] bis(carbamate)] is a fungicide registered for use on vegetables, fruits, soybeans, nuts, and wheat, and ornamental plantings.



Empirical Formula:	C <sub>12</sub> H <sub>14</sub> N <sub>4</sub> O <sub>4</sub> S <sub>2</sub>
Molecular Weight:	342.4
CAS Registry No.:	23564-05-8
Shaughnessy No.:	102001

### IDENTIFICATION OF ACTIVE INGREDIENT

Pure thiophanate-methyl is a colorless crystalline solid with a melting point of 163 EC with decomposition. Technical thiophanate-methyl is a pale brown powder which begins to decompose at - 163 EC. Thiophanate-methyl is slightly soluble in water (21.8 ppm) and sparingly soluble in most organic solvents at 25 EC (2.9 g/100 mL acetone; 7.8 x 10<sup>-1</sup> g/100 mL methanol; 8.4 x 10<sup>-1</sup> g/100 mL ethyl acetate; 7.3 x 10<sup>-2</sup> g/100 mL dichloromethane; 1.8 x 10<sup>-2</sup> g/100 mL n-octanol; 1.1 x 10<sup>-2</sup> g/100 mL xylene; and 4.7 x 10<sup>-5</sup> g/100 mL n-hexane).

### MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 2/11/00 identified a single thiophanate-methyl manufacturing-use product (MP) registered under Shaughnessy No. 102001: the Elf Atochem North America 97% T (EPA Reg. No. 4581-280). Because thiophanate-methyl is a List B chemical, only the 97% T/TGAI is subject to a reregistration eligibility decision.

## REGULATORY BACKGROUND

The Thiophanate-Methyl Phase 4 Review dated 10/18/90 by J. Smith determined that the available data for all pertinent product chemistry guidelines met the acceptance criteria for Phase 5 review.

The current status of the product chemistry data requirements for the thiophanate-methyl technical product is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

## CONCLUSIONS

Most pertinent data requirements are satisfied for the thiophanate-methyl 97% T/TGAI; however, additional data are required concerning OPPTS 830.1620, 830.1670, and 830.6313. In addition, data are required concerning UV/visible absorption for the PAI (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the 97% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the thiophanate-methyl TGAI have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of thiophanate-methyl with respect to product chemistry data requirements.

## AGENCY MEMORANDA CITED IN THIS DOCUMENT

HED No(s):	17882
DP Barcode(s):	D235376
Subject:	Thiophanate-methyl - Product Chemistry Data
From:	L. Cheng
To:	Karen Whitby
Dated:	6/17/97
MRID(s):	40053201-40053205, 40053207, 41482801-41482803, and 41608901-41608909

## PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

### References (cited):

40053201 Watanabe, I. (1986) Thiophanate-methyl - Product Identity and Disclosure of Ingredients: Study No. TL-6181. Unpublished study prepared by Nippon Soda Co., Ltd., Takaoka Laboratory. 6 p.

40053202 Watanabe, I. (1986) Thiophanate-methyl - Description of Beginning Materials and Manufacturing Process: Study No. TL-6182. Unpublished study prepared by Nippon Soda Co., Ltd., Takaoka Laboratory. 13 p.

40053203 Watanabe, I. (1986) Thiophanate-methyl - Discussion of Formation of Impurities: Study No. TL-6183. Unpublished study prepared by Nippon Soda Co., Ltd., Takaoka Laboratory. 12 p.

40053204 Watanabe, I. (1986) Thiophanate-methyl - Density, Bulk Density or Specific Gravity: Study No. TL-6194. Unpublished study prepared by Nippon Soda Co., Ltd., Takaoka Laboratory. 5 p.

40053205 Soeda, Y.; Shiotani, H. (1986) Thiophanate-methyl - Solubility in Water: Study No. NISSO EC-62. Unpublished study prepared by Nippon Soda Co., Ltd., Environmental Toxicology Laboratory. 10 p.

40053207 Soeda, Y.; Shiotani, H. (1986) Thiophanate-methyl - Octanol/Water Partition Coefficient: Study No. NISSO EC-63. Unpublished study prepared by Nippon Soda Co., Ltd., Environmental Toxicology Laboratory. 13 p.

41482801 Ishihara, K. (1990) Thiophanate-methyl Solubility in Organic Solvents: Lab Project I.D.: EC-223. Unpublished study prepared by Nippon Soda Co., Ltd., Odawara Research Center. 11 p.

41482802 Ishihara, K. (1990) Thiophanate-methyl Vapor Pressure: Lab Project Number: EC/224. Unpublished study prepared by Nippon Soda Co., Ltd., Odawara Research Center. 13 p.

41482803 Ishihara, K. (1990) Thiophanate-methyl Dissociation Constant: Lab Project I.D.: EC-225. Unpublished study prepared by Nippon Soda Co., Ltd. 12 p.

41608901 Iguchi, K. (1990) Thiophanate-methyl - Preliminary Analysis of Product Samples: Lab Project Number: TR-896201. Unpublished study prepared by Nippon Soda Co., Ltd. 9 p.

41608902 Iguchi, K. (1990) Thiophanate-methyl - Certification of Ingredient Limits: Lab Project Number: TR-896202. Unpublished study prepared by Nippon Soda Co., Ltd. 9 p.

41608903 Iguchi, K. (1990) Thiophanate-methyl - Analytical Methods to Verify Certified Limits: Lab Project Number: TR-896203. Unpublished study prepared by Nippon Soda Co., Ltd. 31 p.

41608904 Nakayama, K. (1990) Thiophanate-methyl - Color: Lab Project Number: TR-896302. Unpublished study prepared by Nippon Soda Co., Ltd. 8 p.

41608905 Nakayama, K. (1990) Thiophanate-methyl - Physical State: Lab Project Number: TR-896303. Unpublished study prepared by Nippon Soda, Ltd. 8 p.

41608906 Nakayama, K. (1990) Thiophanate-methyl-Odor: Lab Project Number: TR-896304. Unpublished study prepared by Nippon Soda Co., Ltd. 8 p.

41608907 Nakayama, K. (1990) Thiophanate-methyl - Melting Point: Lab Project Number: TR-896305. Unpublished study prepared by Nippon Soda Co., Ltd. 8 p.

41608908 Nakayama, K. (1990) Thiophanate-methyl-pH: Lab Project Number: TR-896312. Unpublished study prepared by Nippon Soda Co., Ltd. 8 p.

41608909 Nakayama, K. (1990) Thiophanate-methyl-Stability: Lab Project Number: TR-896313. Unpublished study prepared by Nippon Soda Co., Ltd. 11 p.

Case No. 2680  
Chemical No. 102001

Case Name: Thiophanate-methyl  
Registrant: Elf Atochem North America, Incorporated  
Product(s): 97% T (EPA Reg. No. 4581-280)

#### PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>1</sup>	MRID Number <sup>2</sup>
830.1550	Product Identity and Disclosure of Ingredients	Y	40053201
830.1600	Starting Materials and Manufacturing Process	N <sup>3</sup>	40053202
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	N <sup>4</sup>	40053203
830.1700	Preliminary Analysis	Y	41608901
830.1750	Certification of Ingredient Limits	Y	41608902
830.1800	Analytical Methods to Verify the Certified Limits	Y	41608903
830.6302	Color	Y	41608904
830.6303	Physical State	Y	41608905
830.6304	Odor	Y	41608906
830.6313	Stability	N <sup>5</sup>	41608909
830.7000	pH	Y	41608908
830.7050	UV/Visible Absorption	N <sup>6</sup>	
830.7200	Melting Point/Melting Range	Y	41608907
830.7220	Boiling Point/Boiling Range	N/A <sup>7</sup>	
830.7300	Density/Relative Density/Bulk Density	Y	40053204
830.7370	Dissociation Constant in Water	Y	41482803
830.7550	Partition Coefficient (Octanol/Water)	Y	40053207
830.7560			
830.7570			
830.7840	Solubility	Y	40053205, 41482801
830.7860			
830.7950	Vapor Pressure	Y	41482802

<sup>1</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>2</sup> All references were reviewed under HED No. 17882, D235376, currently under review.

<sup>3</sup> Information concerning any purification procedures (recovery or recycling) and a description of the procedures used to assure consistent composition of the substance produced are required.

<sup>4</sup> A discussion of the potential for formation of post-production impurities (via degradation, post-production reactions between ingredients, migration of packaging materials into the product, or contamination from production equipment) is required.

<sup>5</sup> Data pertaining to stability on exposure to metal ions are required if the product may be exposed to metals during storage or use.

<sup>6</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>7</sup> Data are not required because the TGAI is a solid at room temperature.

# THIOPHANATE-METHYL

## REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 102001; Case 2680

(HED No. 17601; DP Barcode D230335)

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# THIOPHANATE-METHYL

## REREGISTRATION ELIGIBILITY DOCUMENT

### RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 102001; Case 2680

#### INTRODUCTION

Thiophanate-methyl [dimethyl [(1,2-phenylene)bis(iminocarbonothioyl)]bis(carbamate)] is a systemic fungicide registered for use on numerous crops (See Table A). Thiophanate-methyl is manufactured by Elf-Atochem North America, Inc., the basic producer, under the trade name Topsin®. Thiophanate-methyl formulations registered for use on food/feed crops include dust (D), granular (G), wettable powder (WP), water-dispersible granular (WDG), and flowable concentrate (FIC) formulations. The D formulation may be applied to potato seed-pieces at planting and the G formulation may be applied as an in-furrow application to beans at planting. The remaining products may be applied as an in-furrow application at planting to onions (WP and WDG) or as postemergence broadcast applications to all other labeled crops using ground or aerial equipment.

As indicated in the December 17, 1998 SMART meeting, the following uses are being supported by Elf-Atochem: almonds; apples; beans, dry; beans, lima and snap; cucurbits; bananas; onions; peanuts; pecans; soybeans; apricots; cherries; nectarines; peaches; plums and prunes; strawberries; sugar beets; fall seeded wheat; potatoes (seed treatment only).

The registrant stated that the following uses will not be supported: celery; post harvest uses on all commodities; and sugarcane.

#### REGULATORY BACKGROUND

Thiophanate-methyl is a list B reregistration chemical and was the subject of a Phase IV Review dated 10/18/90 (J. Smith). This document summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Numerous submissions of data have been received since the Phase IV Review was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of thiophanate-methyl.

The HED Metabolism Committee (S. Funk, 3/6/97) concluded that the residues to be regulated in plant and animal commodities for purposes of tolerance enforcement consist of thiophanate-methyl and its metabolite methyl 2-benzimidazolyl carbamate (MBC). For purposes of dietary risk assessment, the residues of concern in plants will include thiophanate-methyl, MBC, and 2-aminobenimidazole (2-AB). In animal commodities, the residues of concern will include thiophanate-methyl, MBC, and the hydroxylated metabolites of MBC (4-OH-MBC, 5-OH-MBC, and 5-OH-MBC-S). The chemical names and structures of these compounds are

depicted in Figure A.

Tolerances for thiophanate-methyl residues in/on plant and livestock raw agricultural commodities (RACs) are **currently** expressed in terms of thiophanate-methyl, its oxygen analogue [dimethyl-4,4'-o-phenylene bis(allophanate)], and its benzimidazole-containing metabolites, (calculated as thiophanate-methyl) [40 CFR § 180.371]. A feed additive tolerance has also been established for thiophanate-methyl residues in dried apple pomace [40 CFR § 186.5700].

Tolerances have been established for thiophanate-methyl residues in plants (almonds, cucumbers, melons, and squash) commodities at 0.1 ppm; apricots, cherries, nectarines, peaches, peanuts, plums, prunes, and sugar beets at 15 ppm for pre and post harvest; apples at 7 ppm; strawberries at 5 ppm; and beans and soybeans at 0.2 ppm [40 CFR § 180.371].

Tolerances have been established for thiophanate-methyl residues in ruminant (cattle, goats, and sheep) commodities at 0.1 ppm (N) in fat, meat, and meat-by-products (exc. liver and kidney), 2.5 ppm in liver, 0.2 ppm in kidney, and 1.0 ppm in milk [40 CFR § 180.371]. Tolerances have also been established for thiophanate-methyl residues in hog and horse commodities at 0.1 ppm (N) in fat, meat, and meat-by-products (exc. liver) and 1.0 ppm in liver. For poultry commodities, tolerances have been established at 0.1 ppm (N) in fat, meat, and meat-by-products (exc. liver), 0.2 ppm (N) in liver, and 0.1 ppm (N) in eggs.

Adequate methods are not available for the enforcement of established tolerances, as currently defined.

Figure A. Chemical names and structures of thiophanate-methyl and its metabolites of concern in plants and animals.

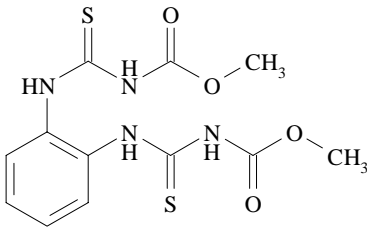
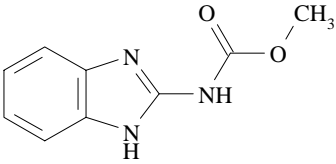
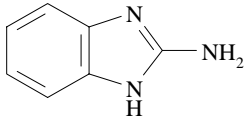
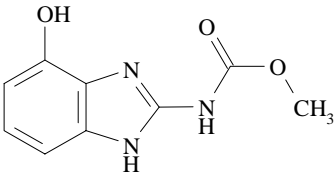
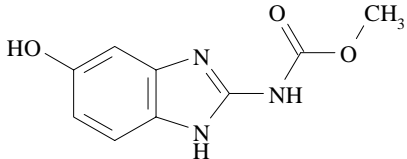
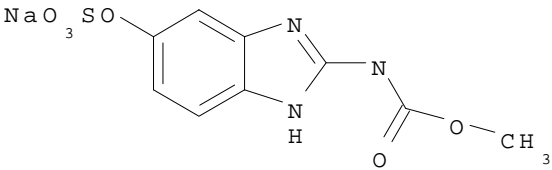
Common Name/Chemical Name	Chemical Structure
<b>Thiophanate-methyl</b>  dimethyl [(1,2-phenylene)bis (iminocarbonothioyl)]bis(carbamate)	

Figure A. Continued.

Common Name/Chemical Name	Chemical Structure
<b>MBC</b>  Carbendazim  Methyl 2-benzimidazolylcarbamate	
<b>2-AB</b>  2-Aminobenzimidazole	
<b>4-OH-MBC</b>  Methyl 2-(4-hydroxybenzimidazolyl) carbamate	
<b>5-OH-MBC</b>  Methyl 2-(5-hydroxybenzimidazolyl) carbamate	
<b>5-OH-MBC-S</b>  sodium 5-(2-methoxycarbonylamino) benzimidazolyl sulfate	

## SUMMARY OF SCIENCE FINDINGS

### OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 2/11/00 indicates that there are six thiophanate-methyl end-use products (EPs) with feed/food uses registered to Elf-Atochem North America, Inc. These EPs are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
4581-322 <sup>a</sup>	10/96	70 % WP	Topsin® M 70W
4581-344 <sup>b</sup>	1/83	5% D	Topsin® M 5D
4581-352 <sup>b</sup>	10/96	4.5 lb/gal FLC	Topsin® M 4.5F
4581-369 <sup>b</sup>	5/94	5% G	Topsin® M 5G
4581-372 <sup>b</sup>	10/96	85% WDG	Topsin® M 85WDG
4581-377 <sup>a</sup>	10/96	70% WP	Topsin® M WSB

<sup>a</sup> Products actively produced and sold by Elf Atochem.

<sup>b</sup> Dormant products not currently in production but registered by Elf Atochem.

There are Special Local Need (24(c)) registrations associated with the active products.

A review of the above labels and supporting residue data indicate that the following label amendments are required:

Use directions for apples, beans (dry and succulent), cucurbit vegetables, and soybeans should be amended to include pre-harvest intervals (PHIs) that are supported by the residue data. The available residue data support a 1-day PHI for apples, a 14-day PHI for succulent beans, and a 28-day PHI for dry beans. The registrant (in a letter dated 9/7/00) has stated that EPA approved application by underground drip irrigation for cucurbits. HED has no documentation that this application method has been approved for cucurbits.

Use directions for apples, apricots, cherries, cucurbit vegetables, nectarines, peaches, peanuts, pecans, plums/prunes, and sugar beets must be amended to indicate a maximum seasonal use rate for each crop. These can be listed as either the maximum number of applications allowed per season or as the maximum amount (lb ai/A) of thiophanate-methyl allowed per season. The maximum seasonal use rates must be supported by the available residue data. The available residue data support the following seasonal use rates: apples - 5.6 lb ai/A/season or eight applications; beans - 2.8 lb ai/A/season or two applications; cherries, peaches, plums, and nectarines - 5.25 lb ai/A/season or five applications.

The maximum use rate for apples should be amended to 0.7 lb ai/A/application, which is supported by the available residue data.

Acceptable residue data are available to support a use on dry bulb onions and garlic. If the registrant does not intend to support the use of thiophanate-methyl on green onions, labels should be amended to restrict this use only to bulb onions and garlic.

In addition, use directions for beans should be amended to exclude the use of thiophanate-methyl on cowpeas.

All labels should be amended by deleting the following statement: "do not allow livestock to graze in treated area prior to harvesting".

All labels should be amended to state that thiophanate methyl can only be rotated to crops with established tolerances. Plant-back intervals for other crops will be determined upon submission of limited field rotational crop studies.

A comprehensive summary of the registered use patterns of thiophanate-methyl, based on the product labels registered to Elf-Atochem, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of thiophanate-methyl is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of thiophanate-methyl food/feed uses are based on the use patterns registered by the basic producer, Elf Atochem North America, Inc. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producers labels.

#### OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on adequate apple, lima bean, sugar beet, and wheat metabolism studies. The HED Metabolism Committee (S. Funk, 3/6/97) concluded that the residues of concern in plants include thiophanate-methyl and its metabolites MBC and 2-AB. For purposes of tolerance enforcement, the regulated residues consist of thiophanate-methyl and MBC. For dietary risk assessment, 2-AB will be included with the parent and MBC. Concentrations of 2-AB in plant commodities will be estimated using the ratio of 2-AB to thiophanate-methyl or MBC in the various plant commodities from the metabolism studies along with residue data for thiophanate-methyl and MBC.

#### OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in animals is understood based upon adequate ruminant and poultry metabolism studies. The HED Metabolism Committee (S. Funk, 3/6/97) concluded that the residues of concern in animal commodities include thiophanate-methyl, MBC, and the hydroxylated derivatives of MBC (4-OH-MBC, 5-OH-MBC, and 5-OH-MBC-S). For purposes of tolerance enforcement, the regulated residues consist of thiophanate-methyl and MBC. For dietary risk assessment, the hydroxylated MBC metabolites will be included along with the

parent and MBC. Concentrations of 4-OH-MBC, 5-OH-MBC, and 5-OH-MBC-S in animal commodities will be estimated using the ratio of these metabolites to thiophanate-methyl or MBC in the animal commodities from the metabolism studies along with residue data for thiophanate-methyl and MBC.

#### OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for collecting data on thiophanate-methyl, MBC, 2-AB, and the hydroxylated metabolites of MBC residues in plant and animal commodities; however, the requirement for acceptable enforcement methods for plant and animal RACs remains outstanding.

A single enforcement method for determining parent and MBC in plant commodities is listed in the Pesticide Analytical Manual (PAM), Vol. II, as Method I. As this method is a spectrophotometric method, it is no longer considered acceptable for enforcing tolerances. The two additional methods listed in PAM Vol. II, Methods A and B, are also spectrophotometric methods for plant commodities. In addition, Method A is for determining the metabolite allophanate, which is no longer a residue of concern.

The registrant has proposed a HPLC/UV detection method (Elf Atochem Method No. BR-011-04) for enforcing tolerances for thiophanate-methyl residues in/on plant commodities. For this method, residues of thiophanate-methyl and MBC (plus 2-AB) are extracted from plant matrices using acidified methanol, neutralized, partitioned into methylene chloride, and concentrated. For matrices requiring further clean-up, samples are purified using a 1N2Namino SPE column. Residues of thiophanate-methyl and MBC (plus 2-AB) are determined by reverse-phase HPLC using a column switching system consisting of two reverse-phase columns using different solvent systems and a UV detector. The limit of quantitation for both analytes is 0.05 ppm in most plant commodities. In its review of this method (DP Barcodes D214622 and D215191, S. Funk, 6/8/95), the Agency concluded that the method was inadequate, but that it could be upgraded if the registrant adequately addressed the deficiencies noted in the review. The registrant, Elf Atochem, has submitted (1996; MRID 43986601) a revised version of the proposed HPLC/UV enforcement method (Method BR-93-28), along with a letter (1996, MRID 43986600) discussing the revisions and the deficiencies previously noted by the Agency. Upon review of the revised method, HED has concluded the following: a) the deficiencies previously cited by the Agency in the proposed HPLC/UV enforcement method (BR-93-28) for determining residues of TM and MBC in plant commodities have been resolved. Method BR-93-28 is adequate for determining residues of TM and MBC (plus 2-AB) in/on plant commodities and has a limit of quantitation (LOQ) of 0.05 ppm for each analyte; and b) HPLC/UV Method BR-93-28 must still be radiovalidated using samples from a plant metabolism study and undergo a successful independent laboratory validation (ILV) prior to being validated by the Agency. In addition, HED notes that information pertaining to the analysis of the metabolites allophanate (FH-432) and DX-105 should be removed from the method as these metabolites are not being included in the tolerance expression for TM. The registrant has submitted an independent method validation for method BR-93-28 (MRID 44703602). This independent method

validation is currently under review by HED.

Data from analysis of thiophanate-methyl residues in plants have been collected using versions of the proposed enforcement method. Except for minor changes in clean-up procedures and solvent systems, these methods are essentially the same as the proposed enforcement method.

HED has determined that the registrant must also propose an enforcement analytical method for determining residues of concern in animal commodities, validate the method using samples from the animal metabolism studies, and subject the method to an independent laboratory validation. The registrant has submitted an enforcement method for animal commodities and an independent method validation (MRID 44526101). These are currently under review in HED.

Data on residues of thiophanate-methyl, MBC, 4-OH-MBC, 5-OH-MBC, and 5-OH-MBC-S in milk and tissues from the ruminant feeding study were collected using adequate HPLC/UV methods that are modified versions of the above methods for plants. These methods involve extraction of residues into acidic methanol (following acid hydrolysis for milk and kidneys), solvent partitioning, and, if necessary, column clean-up prior to determining residues by reverse-phase HPLC with UV detection. The limit of quantitation for each analyte is 0.05 ppm.

#### OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that thiophanate-methyl and MBC are completely recovered using FDA Multiresidue Protocol A (PAM I Section 242.2). Additional multiresidue method (MRM) recovery data are required for thiophanate-methyl and MBC through FDA MRM protocols A through G.

#### OPPTS GLN 860.1380: Storage Stability Data

Requirements for storage stability data are not satisfied for purposes of reregistration. To support the residue data for plant commodities, data are required depicting the frozen storage stability of thiophanate-methyl and MBC in representative raw and processed plant commodities held in frozen storage for up to 5 years; interim 2-year data should be submitted. The requested storage stability study was begun by the registrant in 2/97. Storage stability data for 2-AB should also be submitted for plant commodities.

Acceptable interim (36 months) storage stability data are available indicating that thiophanate methyl and MBC are stable in apples, cucumbers, lettuce, wheat, carrots, snap beans, spinach, sugar beet roots, tomatoes, and wheat grain stored at -20 EC for up to 3 years.

Data are also required depicting the stability of thiophanate-methyl, MBC, 4-OH-MBC, 5-OH-MBC, and 5-OH-MBC-S in representative animal commodities held in frozen storage for

intervals equivalent to the maximum storage intervals in the ruminant feeding study (milk - 250 days, tissues - 225 days).

Storage stability data for poultry are adequate and indicate that residues of TM, MBC, and 5'-OH-MBC are stable in eggs under frozen conditions for up to 10 months. Residues of 5'-OH-MBC and either TM or MBC are stable in poultry liver or muscle, respectively, for up to 8.5 months. These data adequately support the frozen storage intervals for poultry commodities reflected in the feeding study.

The registrant has stated that on June 18, 1996, EPA met with Elf Atochem to determine what storage stability data would be required to support studies being submitted at that time. At the meeting, the Agency stated that submitted storage stability studies demonstrated that MBC was highly stable when stored frozen and that this data could be extrapolated up to 5 years demonstrating satisfactory stability of MBC. On this basis, the EPA stated that no additional residue data was required for MBC. However, there is no documentation in our files about this meeting or the decision made by EPA. HED will still consider the requirements for storage stability outstanding and they should be fulfilled for reregistration purposes.

#### OPPTS GLN 860.1500: Magnitude of the Residue in Plants

Provided issues pertaining to storage stability of the residues are adequately resolved, reregistration requirements for magnitude of the residue in plants are fulfilled for the following crops/commodities: apple, cucurbit vegetables, cherry, onions (dry bulb), plums (fresh prunes), potatoes, strawberry, and wheat grain. Adequate field trial data depicting residues of thiophanate-methyl and MBC following applications made according to the maximum or proposed federally registered use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

In addition, reregistration requirements for residue studies on beans (dry and succulent) and peaches/nectarines are fulfilled if the registrant amends label directions to specify the application rates and PHIs supported by the available residue data and provide supporting storage stability data.

For purposes of reregistration, residue data are required on almonds, apricots, bananas, dried peas, cucurbit vegetables, peanuts, pecans, potatoes, soybeans, sugar beets, and wheat forage, hay, and straw. Residue data are also required on green onions unless the registrant does not intend to support this use. In which case, the label directions should be modified to restrict the use only to bulb onions and garlic.

The registrant has stated that residue studies were submitted for the following crops: almonds, dry peas, peanuts, pecans, potatoes, soybeans and sugar beets. These studies are currently under review by HED.



#### OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants - Pending Petitions

*PP# 5F4550/6H5734*: Elf Atochem North America has submitted petitions for establishing tolerances for thiophanate-methyl residues in/on grapes at 5 ppm and in/on pears at 7 ppm. The proposed use pattern for grapes specifies multiple foliar applications of thiophanate-methyl (70% WP or 4.5 lb/gal FIC) at a maximum rate of 1.05 lb ai/A/application at a minimum of 14-day intervals. A maximum of six applications are allowed per season and no more than 4.2 lb ai/A can be applied per season. The proposed PHI for grapes is 14 days. The proposed use pattern for pears specifies multiple foliar applications of thiophanate-methyl (70% WP or 4.5 lb/gal FIC) at a maximum rate of 0.7 lb ai/A/application (or 0.175 lb ai/100 gal) at a minimum of 7-day intervals. A maximum of eight applications are allowed per season and no more than 5.6 lb ai/A can be applied per season. The proposed PHI for pears is 1 day.

These petitions are currently in reject status (CBTS Nos. 16281, 16282, 166602, 16603, 16604, 16611; DP Barcodes D209958, F. Griffith, 2/2/96). Although several of the deficiencies cited in this review have since been resolved, deficiencies pertaining to following areas must still be resolved: i) amending the proposed use directions for pears, ii) independent laboratory validation of the proposed analytical enforcement method, iii) multiresidue method testing data, iv) supporting storage stability data, and v) three additional field trials for grapes. The registrant has submitted an independent method validation for method BR-93-28 in plants (MRID 44703602). This independent method validation is currently under review by HED.

#### OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

Provided issues pertaining to storage stability of the residues are resolved, reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apple, plums, and wheat. In addition, an adequate grape processing study is available from a pending petition for a tolerance on residues in/on grapes. The requirements for processing studies on peanuts, potatoes, soybeans, and sugar beets remain outstanding.

Based on the available processing studies, tolerances are not required for residues in processed commodities of apples, grapes, plums, and wheat. Residues did not concentrate in apple juice, grape juice, raisins, and prunes processed from RACs bearing detectable residues. Residues concentrated slightly in wet apple pomace, but not enough to warrant establishing a separate tolerance; two separate analyses of wet pomace indicated that residues concentrated by 1x and 1.4x (1.2x average). For wheat, residues of both thiophanate-methyl and MBC were nondetectable (<0.05 ppm) in/on the wheat grain from two tests in which wheat plants were treated at - 11x the label rate (the maximum theoretical concentration factor for processed wheat fractions is 8.3x for wheat shorts); therefore, a wheat processing study was not conducted.

The registrant has submitted processing studies for the following commodities: peanuts (MRID 44850901), potatoes (MIRD 44498502), soybeans (MRID 44582702) and sugar beets (MRIDs 44643502, 44584601). These studies are currently under review by HED.

## OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Tolerances have been established for thiophanate-methyl residues in ruminant (cattle, goats, and sheep) commodities at 0.1 ppm (N) in fat, meat, and meat-by-products (exc. liver and kidney), 2.5 ppm in liver, 0.2 ppm in kidney, and 1.0 ppm in milk [40 CFR §180.371]. Tolerances have also been established for thiophanate-methyl residues in hog and horse commodities at 0.1 ppm (N) in fat, meat, and meat-byproducts (exc. liver) and 1.0 ppm in liver. For poultry commodities, tolerances have been established for 0.1 ppm (N) in fat, meat, and meat-by-products (exc. liver), 0.2 ppm (N) in liver, and 0.1 ppm (N) in eggs.

Using established or reassessed tolerances of thiophanate-methyl residues in/on animal feed items, the calculated theoretical dietary burdens for livestock that were used in calculating the reassessed animal tolerances are presented below:

Feed Commodity	% Dry Matter <sup>a</sup>	% Diet <sup>a</sup>	Reassessed Tolerance (ppm) <sup>b</sup>	Dietary Contribution (ppm) <sup>c</sup>
<b>Beef Cattle</b>				
sugar beet tops	23	20	15.0	13.0
peanut hay	85	25	15.0	4.41
wet apple pomace	40	20	2.0	1.00
almond hulls	90	10	1.0	0.11
peanut meal	85	15	0.2	0.04
wheat grain	89	10	0.05	0.01
TOTAL BURDEN		100		<b>18.57</b>
<b>Dairy Cattle</b>				
peanut hay	85	25	15.0	4.41
sugar beet tops	23	10	15.0	6.52
wet apple pomace	40	20	2.0	1.00
soybean meal	92	15	0.2	0.03
almond hulls	90	10	1.0	0.11
wheat grain	89	20	0.05	0.01
TOTAL BURDEN		100		<b>12.08</b>
<b>Swine</b>				
soybeans	N/A	25	0.2	0.05
wheat grain	N/A	75	0.05	0.04
TOTAL BURDEN		100		<b>0.09</b>

<sup>a</sup> Table 1, OPPTS GLN 860.1000.

<sup>b</sup> Established or reassessed tolerances from Table C.

<sup>c</sup> Contribution = [tolerance / %DM (if cattle)] X % diet).

For poultry, (MRID 44287501, 2/12/98) dosages of 0.4 ppm (2.1x), 1.3 ppm (6.4x), and 4.3 ppm (21x) in the dry feed given to the hens did not accumulate to produce residues above the LOQ of 0.05 ppm. Therefore, poultry and eggs were not included in the dietary risk assessment. The results are shown in the following Table.

<b>Raw Agricultural Commodity</b>	<b>Thiophanate Methyl Tolerance (ppm)</b>	<b>% Poultry Diet</b>	<b>Thiophanate-methyl Contribution (ppm)</b>
peanut meal	0.2	25	0.05
soybean meal	0.2	40	0.08
soybean hulls	0.2	20	0.04
soybean seed	0.2	15	0.03
TOTAL		100	0.20

Provided that the registrant submits adequate supporting storage stability data for the residues of concern in animal commodities, an adequate ruminant feeding study is available reflecting the dosing of dairy cattle for 28 days at levels equivalent to 67.1, 205, and 839 ppm in the diet (approximately 3.6x, 11x and 45x the theoretical dietary burden for beef cattle).

Based upon the results of this study and the LOQs of thiophanate-methyl and MBC (0.05 ppm) in milk and tissues, tolerances for residues in milk and in fat, meat, and meat-by-products of cattle, goats, horses, and sheep should be reassessed to 0.15 ppm.

Considering the maximum theoretical dietary burden for swine (0.09 ppm) and the results of the ruminant feeding study, the Agency also concludes that a 40 CFR §180.6(a)(3) situation exists with respect to thiophanate-methyl and MBC residues in hog commodities. Therefore, tolerances for residues in hog commodities should be revoked.

In the poultry feeding studies, residues of TM, MBC, and 5'-OH-MBC were each <0.05 ppm, (<LOQ) at a dosing level equivalent to 21x the calculated maximum theoretical dietary burden. These data indicate that there is no reasonable expectation of residues [40 CFR §180.6(a)(3)] in poultry commodities. The currently established tolerances for residues of TM in poultry commodities should be revoked.

#### OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, and Irrigated Crops

Thiophanate-methyl is presently not registered for direct use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

#### OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Thiophanate-methyl is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

#### OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

The existing confined rotational crop study is inadequate, but can be upgraded by the submission of additional information/data. Data are required characterizing/identifying <sup>14</sup>C-residues in rotated carrots, along with supporting storage stability information/data. For the storage stability information/data, the registrant must provide: i) storage intervals (harvest to extraction) for each rotational crop from each plant-back interval; and ii) details of the extraction and analysis of 30-DAT wheat forage and chaff (mature and immature) at different time intervals along with copies of chromatograms or TLC profiles.

Adequate data have been submitted characterizing <sup>14</sup>C-residues in rotated lettuce, carrots, and wheat; metabolism in these rotational crops is similar to the metabolism in the primary crops. Parent, thiophanate-methyl, levels were <0.01 ppm in all crops. Thiophanate-methyl residues of concern (MBC and 2-AB) were found at levels of >0.01 ppm in lettuce from 30- and 120-day plant-back intervals and in wheat from 30- and 365-day plant-back intervals, indicating that limited rotational field trials are required. Thiophanate-methyl residues of concern (MBC and 2-AB) were found at levels of <0.01 ppm in carrot from 30- and 120-day plant-back intervals. In the confined rotation crop studies, [<sup>14</sup>C]thiophanate-methyl was applied to the soil at 1.4 lb ai/A, which was the stated 1x the maximum single application rate. However, the maximum single application rate for onions is higher (11.2 lb ai/A) as are the seasonal application rates for several crops (e.g. beans - 2.8 lb ai/A/season).

#### OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

As residues of concern (MBC and 2-AB) were detected at >0.01 ppm in lettuce and wheat from 30- to 365-day plant-back intervals in the confined rotational crop study, limited field rotational crop studies are required. Limited field studies should be conducted at two separate test sites using a representative root and tuber vegetable, leafy vegetable, and small grain crop at each site. In accordance with the guidance provided in OPPTS GLN 860.1900, the rotational crops should be planted at the desired rotational crop interval following the maximum number of applications of thiophanate-methyl at the maximum label rate. Residues of thiophanate-methyl and MBC should be determined in the appropriate RACs from each rotational crop.

TABLE A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR THIOPHANATE-METHYL (CASE 2680).

Site Application Type Application Timing Application Equipment <sup>a</sup>	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations <sup>b</sup>
<b>Almonds</b>					
Broadcast applications at flowering Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.4 lb/A	2 <sup>c</sup>	NS = not specified	No PHI is specified. A maximum of 2 applications/season are implied by the label directions.
<b>Apples</b>					
Broadcast foliar application Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.05 lb/A	NS	7 (5 days during flowering)	Labels do not specify a PHI, maximum number of applications/season, or maximum seasonal use rate.  The label for the 85% WDG allow a maximum application rate of 2.8 lb ai/A in the following Southeastern states: FL, GA, SC, NC, and AL
<b>Apricots</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] [SC790033] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.05 lb/A	NS	10	A 1-day PHI is specified. Labels do not specify a maximum number of applications/season or maximum seasonal use rate.

Table A. Continued.

Site Application Type Application Timing Application Equipment <sup>a</sup>	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations <sup>b</sup>
<b>Beans (dry and succulent)</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [581-352]	2 lb/A	2 <sup>c</sup>	4-7	CA only: 14-day PHI snap beans and a 28-day for lima beans. For all other states: 14 day PHI for snap and lima beans. PHI for dry beans is 28 days.
In-furrow application at planting Ground equipment	5% G [581-369] 70% WP [MI860001]	1.4 lb/1,000 ft row	1	NS	The labels do not specify a PHI as this application can only be made at planting.
<b>Cherry</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] [SC790033] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.05 lb/A	NS	10	A 1-day PHI is specified. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.

Table A. Continued.

Site Application Type Application Timing Application Equipment <sup>a</sup>	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations <sup>b</sup>
<b>Cucurbit vegetables</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372]	0.35 lb/A	NS	7	Labels do not specify a PHI, maximum number of applications/season, or maximum seasonal use rate.
<b>Nectarines</b>					
Broadcast foliar applications Ground or aerial equipment	70% WP [4581-322] [4581-377] [SC790033] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.05 lb/A	NS	10	A 1-day PHI is specified. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.
<b>Onions</b>					
In-furrow application or broadcast at planting Ground equipment	85% WDG [4581-372] 70 % WP [4581-322] [4581-377]	0.35 lb/1,000 ft row or 11.2 lb/A	1 <sup>c</sup>	NA = not applicable	No PHI is specified. Do not apply through any type of irrigation system. Only the 70% WP formulations allow a broadcast application.
<b>Peaches</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] [SC790033] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.6 lb/A	NS	10	A 1-day PHI is specified. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.
<b>Peanuts</b>					

Table A. Continued.

Site Application Type Application Timing Application Equipment <sup>a</sup>	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations <sup>b</sup>
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	0.35 lb/A	NS	14	A 14-day PHI is specified. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.
<b>Pecans</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	0.7 lb/A	NS	21	Do not apply after shuck split. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.
<b>Plums/Prunes</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] [SC790033] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	1.05 lb/A	NS	10	A 1-day PHI is specified. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.
<b>Potatoes</b>					
Treatment of seed-pieces prior to planting.	5% D [4581-344]	0.7 lb/100 lb of cut pieces	1	NA	Do not use seed pieces for food, feed, or fodder.



Table A. Continued.

Site Application Type Application Timing Application Equipment <sup>a</sup>	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations <sup>b</sup>
<b>Soybeans</b>					
Broadcast foliar applications beginning at full bloom. Ground and aerial equipment	70% WP [4581-322] [4581-377] [MS840014] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	0.7 lb/A	2	14	A PHI is not specified; applications later than 14 days after pods average ¼ inch in length are prohibited. Do not make more than 2 applications per season. Do not graze or feed treated vines or hay to livestock.
<b>Strawberries</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	0.7 lb/A	NS	7	A 1-day PHI is specified. Do not apply more than 2.8 lb ai/A/season.
<b>Sugar Beets</b>					
Broadcast foliar applications Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	0.35 lb/A	NS	14	A 21-day PHI is specified. Labels do not specify a maximum seasonal application rate or a maximum number of applications per season.

Table A. Continued.

Site Application Type Application Timing Application Equipment <sup>a</sup>	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations <sup>b</sup>
<b>Wheat</b> (fall-seeded only in ID, OR, and WA)					
Broadcast application at tillering prior to stem elongation Ground and aerial equipment	70% WP [4581-322] [4581-377] 85% WDG [4581-372] 4.5 lb/gal FIC [4581-352]	0.7 lb/A	1	NA	<sup>d</sup> Do not make more than one application per season. Do not cut for hay within 90 days of application or allow livestock to graze in treated area prior to harvest.

<sup>a</sup> Unless specifically prohibited, ground applications can include chemigation using center pivot, lateral move end tow, side (wheel) roll, traveler, big gun, solid set, or hand move sprinkler systems (EPA Reg Nos. 4581-322, 4581-352, 4581-372, and 4581-377).

<sup>b</sup> All labels specify a 12-hour restricted entry interval (REI). None of the labels specify plant-back intervals for crops planted after field crops that were treated with thiophanate-methyl.

<sup>c</sup> Maximum number of applications is not specifically stated on the label(s), but is implied from the use directions.

<sup>d</sup> The best means to explain wheat growth stages is to use the Feeke's Growth Stage Designations. A separate paper discussing the Feeke's growth stages is being prepared for CHEMSAC review. So, the label translate to tillering (Feeke's stage 2.0) prior to stem elongation (Feeke's stage 3.0). This treatment would occur in March. Table 1 of the Residue Chemistry Guidelines states for wheat hay to sample from early flowering boot stage (Feeke's stage 10.0) to the soft dough stage (Feeke's stage 11.2). In actual days these stages would be May 15- early June or approximately 60 to 90 days after the pesticide application. Harvest would occur at Feeke's stage 11.4 (late June to early end July). In these three states the harvest period can extend to mid August. Therefore, the limitation for do not cut for hay within 90 days of treatment would place the residue sample at the extreme end of the Table 1 sampling time. The optimum samples for residue analysis are between 60-90 days after application. The other part of the limitation "do not allow livestock to graze in treated area prior to harvesting makes no sense, since standard agronomic practice is to graze at the tillering stages and ends at early spring, which is the exact growth stage that wheat would be treated. If the crop is grown for grain they must be removed from the field in the early stem elongation stage (Feeke's stages 5.0, 6.0).

Table B. Residue Chemistry Science Assessments for Reregistration of Thiophanate-methyl.

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
860.1200: Directions for Use	N/A	Yes <sup>2</sup>	See Table A.
860.1300: Nature of the Residue			
- Plants	N/A	No	42298103 <sup>3</sup> 42492501 <sup>4</sup> 42513701 <sup>4</sup> 42533801 <sup>5</sup> 43337801 <sup>6</sup> 44103201 <sup>7</sup> 44103202 <sup>7</sup>
- Livestock	N/A	No	42472101 <sup>8</sup> 42472102 <sup>8</sup> 42658301 <sup>9</sup> 42874101 <sup>10</sup> 42995001 <sup>11</sup> 43095701 <sup>12</sup> 43137801 <sup>12</sup> 43137802 <sup>12</sup> 43019201 <sup>12</sup>
860.1340: Residue Analytical Methods	N/A	Yes <sup>13</sup>	42683601 <sup>14</sup> 43521901 <sup>15</sup> 43624801 <sup>15</sup> 43986601 <sup>16</sup> 44523101 <sup>13</sup> 44703602 <sup>13</sup>
860.1360: Multiresidue Method	N/A	Yes <sup>17</sup>	
860.1380: Storage Stability	N/A	Yes <sup>18</sup>	43948201 <sup>19</sup> 44533302 <sup>20</sup> 44533301 <sup>20</sup> 44533303 <sup>20</sup> 44533304 <sup>20</sup> 44471401 <sup>21</sup> 44401801 <sup>22</sup> 44401802 <sup>22</sup> 44401803 <sup>22</sup> 44401804 <sup>22</sup> 44400001 <sup>22</sup>
860.1500: Magnitude of the Residue in Crop Plants			
<u>Root and Tuber Vegetables Group</u>			
- Potatoes	0.05 [§180.371]	No	44468202 <sup>23</sup>
- Sugar beets	0.2 [§180.371]	Yes <sup>24</sup>	44643501 <sup>25</sup>
<u>Leaves of Root and Tuber Vegetables Group</u>			
- Sugar beet, tops	15.0 [§180.371]	Yes <sup>24</sup>	44643501 <sup>25</sup>
<u>Bulb Vegetables (<i>Allium spp.</i>) Group</u>			
- Onions, dry	3.0 [§180.371]	No	44148201 <sup>19</sup>
- Onions, green	3.0 [§180.371]	Yes <sup>26</sup>	
<u>Leafy Vegetables (excluding Brassica) Group</u>			
- Celery	3.0 [§180.371]	No <sup>27</sup>	
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Beans, dry	2.0 [§180.371]	Yes <sup>28</sup>	44286701 <sup>29</sup> 44161001 <sup>19</sup>

Table B *(continued)*.

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
- Beans, snap	2.0 [§180.371]	No	44184301 <sup>19</sup>
- Soybeans	0.2 [§180.371]	Yes <sup>30</sup>	44572701

Table B (continued).

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
<u>Foliage of Legume Vegetables Group</u>			
- Beans, forage and hay	50.0 [§180.371]	No <sup>31</sup>	
<u>Cucurbit Vegetables Group</u>			
- Cucumbers	1.0 [§180.371]	No	44471401 <sup>32</sup>
- Melons	1.0 [§180.371]	No <sup>23</sup>	44468201
- Pumpkins	1.0 [§180.371]	No <sup>23</sup>	
- Squash	1.0 [§180.371]	No	44467901 <sup>33</sup>
<u>Pome Fruits Group</u>			
- Apples	7.0 [§180.371]	No <sup>34</sup>	43516301 <sup>35</sup>
- Pears	None	No	43750902 <sup>36</sup>
<u>Stone Fruits Group</u>			
- Apricots	15.0 [§180.371]	Yes <sup>37</sup>	
- Cherries	15.0 [§180.371]	No <sup>38</sup>	44182401 <sup>19</sup>
- Peaches/Nectarines	15.0 [§180.371]	No <sup>38</sup>	44083801 <sup>19</sup>
- Plums	15.0 [§180.371]	No <sup>39</sup>	44036301 <sup>40</sup>
<u>Tree Nuts Group</u>			
- Almonds	0.2 (N) [§180.371]	Yes <sup>41</sup>	44487001
- Almonds, hulls	1.0 [§180.371]	Yes <sup>41</sup>	
- Pecans	0.2 [§180.371]	Yes <sup>42</sup>	44498501
<u>Cereal Grains Group</u>			
- Wheat, grain	0.05 [§180.371]	No	40324701 <sup>43</sup> 44162001 <sup>19</sup> 44106901
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- Wheat hay and straw	0.1 [§180.371]	Yes <sup>44</sup>	44162001 <sup>19</sup>

Table B (continued).

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
<u>Miscellaneous Commodities</u>			
- Bananas	2.0 [§180.371]	Yes <sup>45</sup>	
- Bananas, pulp	0.2 [§180.371]	No <sup>45</sup>	
- Grapes	None	Yes <sup>46</sup>	43750901 <sup>36</sup>
- Peanuts	0.2 (N) [§180.371]	Yes <sup>47</sup>	44515701
- Peanuts, forage and hay	15.0 [§180.371]	Yes <sup>47</sup>	
- Peanuts, hulls	2.0 [§180.371]	No	
- Strawberries	5.0 [§180.371]	No	44228801 <sup>48</sup>
860.1520: Magnitude of the Residues in Processed Food/Feed			
- Apple, pomace, dried	40.0 [§186.5700]	No	43591901 <sup>49</sup> 44073301 <sup>19</sup>
- Grape	None	No	43701701 <sup>36</sup>
- Peanut	None	Yes <sup>50</sup>	44850901
- Prunes	15.0 [§180.371]	No	43887101 <sup>19</sup>
- Potato	None	Yes <sup>50</sup>	44498502
- Soybean	None	Yes <sup>50</sup>	44572702
- Sugar beet	None	Yes <sup>50</sup>	44584601
- Wheat	None	No	44106901 <sup>19</sup>
860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Milk	1.0 [§180.371]	No <sup>51</sup>	44232401 <sup>48</sup> 44592301 44287501
- Fat, meat, and mbyp (exc. kidney and liver) of cattle, goats, hogs, horses, and sheep	0.1 (N) [§180.371]	No <sup>51</sup>	44232401 <sup>48</sup>
- Liver of cattle, goats, and sheep	2.5 [§180.371]	No <sup>51</sup>	44232401 <sup>48</sup>
- Liver of hogs and horses	1.0 [§180.371]	No <sup>51</sup>	44232401 <sup>48</sup>
- Kidneys of cattle, goats and sheep	0.2 [§180.371]	No <sup>51</sup>	44232401 <sup>48</sup>
- Eggs	0.1 (N) [§180.371]	No	44643502 <sup>52</sup>
- Fat, meat, and mbyp (exc. liver) of poultry	0.1 (N) [§180.371]	No	44643502 <sup>52</sup>

Table B (continued).

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
- Liver of poultry	0.2 (N) [§180.371]	No	44643502 <sup>52</sup>
860.1400: Magnitude of the Residue in water, fish, and irrigated crops	N/A	N/A	
860.1460: Magnitude of the Residue in Food Handling Establishments	N/A	N/A	
860.1850: Confined Accumulation in Rotational Crops	N/A	No	42670501 <sup>52</sup> 44216201 <sup>53</sup> 44115901 <sup>54</sup>
860.1900: Field Accumulation in Rotational Crops	None	Yes <sup>55</sup>	

- References were reviewed as cited.
- Based upon the available residue data and/or changes in data requirements, the Agency is recommending specific changes to label directions for numerous crops. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under OPPTS GLN 860.1200: Directions for Use.
- HED No. 9865, DP Barcode D178252, S. Funk, 7/2/92.
- HED No. 10788, DP Barcode D183907, S. Funk, 12/18/92.
- HED No. 10853, DP Barcode D184518, S. Funk, 12/3/92.
- HED No. 14263, DP Barcode D206837, S. Funk, 9/18/96.
- HED No. 17578, DP Barcode D229851, S. Funk, 11/14/96.
- HED No. 10627, DP Barcode D182853, S. Funk, 11/10/92.
- HED No. 11385, DP Barcode D188134, S. Funk, 4/13/93.
- HED No. 12395, DP Barcode D194267, S. Funk, 10/15/93.
- HED No. 12811, DP Barcode D196593, S. Funk, 12/7/93.
- HED No. 13339, DP Barcode D199837, S. Funk, 3/10/94.
- The enforcement analytical method for plant commodities should be validated using samples from the plant metabolism studies, and undergo an independent laboratory validation prior to validation by the Agency. An independent validation method has been submitted by the registrant and is currently under review by HED (MRID 44703602 for plants and MRID 44523101 for animals).

HED has also concluded that the registrant must also propose an enforcement analytical method for animal commodities, validate the method using samples from the animal metabolism studies, and subject the method to an independent laboratory validation. The registrant has submitted an enforcement method for animal commodities and an independent method validation for this method. These are currently under review by HED.

Table B (*continued*).

14. HED No. 11599, DP Barcode D189303, S. Funk, 8/16/93.
15. HED Nos. 15504 and 15554, DP Barcodes D214622 and D215191, S. Funk, 6/8/95.
16. DP Barcode D225681, L. Cheng, 2/8/99.
17. Multiresidue method (MRM) recovery data are required for thiophanate-methyl and MBC through FDA MRM protocols A through G.
18. Data are required depicting the frozen storage stability of thiophanate-methyl and MBC in representative raw and processed plant commodities held in frozen storage for up to five years; interim 3-year data have been submitted.  
  
Data are also required depicting the stability of thiophanate-methyl, MBC, 4-OH-MBC, 5-OH-MBC, and 5-OH-MBC-S in representative animal commodities held in frozen storage for interval equivalent to the maximum storage intervals in the ruminant feeding study.
19. HED Nos. 16891, 17047, 17411, 17414, 17532, 17561, 17644, 17680, and 17681; DP Barcodes D222642, D224324, D229962, D231210, D231690, D231851, D232400, and D232401; L. Cheng, 6/17/97.
20. DP Barcodes D245784, D245781, D245788, D245791, M. Sahafeyan, 7/22/98.
21. DP Barcodes D243127, D241362, D241363, S. Piper, 6/5/98.
22. DP Barcodes D243127, D241362, D241363, S. Piper, 6/5/98.
23. DP Barcode D243124, S. Piper, 6/29/98.
24. The submitted residue study on sugar beets is inadequate but upgradeable provided that residue data from an additional test conducted in CA are submitted. The registrant conducted two tests in CA, as required by OPPTS GLN 860.1500, one of which was considered invalid by the registrant due to the poor quality of the RAC samples collected; the registrant stated that the trial will be repeated. These replacement data are required as residues of thiophanate-methyl in/on sugar beet tops analyzed from this trial exceeded the established tolerance of 15.0 ppm, and residues from the other CA trial comprised the HAFT.
25. DP Barcodes D240264, D249897, D249898, D251551, currently under review by HED.
26. Data are required depicting residues of thiophanate-methyl and MBC in/on green onions harvested at the minimum interval following a broadcast or in-furrow application at planting of thiophanate-methyl (WP/WDG/FIC) 0.35 lb ai/1,000 ft row or 11.2 lb ai/A. A minimum of three field trials should be conducted; two in Region 10 and one in Region 6. Alternatively, the registrant may amend labels to allow applications only to dry bulb onions and garlic.
27. DP Barcodes D241999, D243120, L. Cheng, 2/4/99. Celery registration has been cancelled by the registrant.
28. The available residue data for dry beans are adequate if the registrant amends the labels to specify a 28-day PHI and if acceptable storage stability data are provided. Residue data for dried peas need to be submitted.



Table B (*continued*).

29. DP Barcodes D240264, D249897, D249898, D251551, currently under review by HED.
30. Data are required depicting residues of thiophanate-methyl and MBC in/on soybeans harvested at maturity following two foliar applications of thiophanate-methyl (WP/WDG and FIC) at 0.7 lb ai/A/application. The first application should be made when pods average  $\frac{1}{4}$  inch in length with the second application 14 days later. A minimum of 20 field trials should be conducted: 2 in Region 2; 3 in Region 4; and 15 in Region 5. At least 15 of these trials should include side-by-side comparisons of applications of a WP/WDG formulation with the FIC formulation. The registrant has submitted residue studies for soybeans and these are currently under review (MRID 44572701).
31. With the exception of cowpea forage and hay, the Agency no longer considers bean forage and hay to be significant livestock feed items. Therefore, unless the registrant intends to specifically support the use of thiophanate-methyl on cowpeas, residue data on bean forage and hay will not be required and the current tolerances for residues in/on these commodities will be revoked.
32. DP Barcodes D243127, D241362, D241363, S. Piper, 6/5/98.
33. The registrant has requested a crop group tolerance for the cucurbit vegetables. To support this crop group tolerance the registrant has submitted representative field trials for the following representative crops: cucumbers, cantaloupes, and summer squash. All of the studies were acceptable and a crop group tolerance will be established for the cucurbit vegetables.
34. The label for the 85% WDG (EPA Reg. No. 4581-372) allows foliar applications at up to 2.8 lb ai/A in the Southeastern states of AL, FL, GA, SC, and NC. The registrant must either delete this use rate from the label or provide four additional apple field trials supporting the higher use rate; one trial each in AL, FL, GA, and NC/SC.
35. HED No. 15472, DP Barcode D214690, S. Funk, 6/8/95; and HED Nos. 13726 and 16783, DP Barcodes D203578 and D222474, S. Funk, 3/25/96.
36. PP#5F4550/6H5734; CBTS Nos. 16281, 16282, 16602-16604, and 16611; DP Barcodes D219884, D219890, D221502, D221593 and D221595; F. Griffith; 2/2/96.
37. Data are required depicting residues of thiophanate-methyl and MBC in/on apricots harvested one day following the last of multiple foliar applications of thiophanate-methyl (WP/WDG and FIC) at 1.05 lb ai/A/application. A minimum of five tests must be conducted, four in Region 10 and one in Region 11. At least 3 of these trials should include side-by-side comparisons of applications of a WP/WDG formulation with the FIC formulation, and at least one of these trials should be a residue decline study that includes 3 to 5 additional sampling intervals in addition to the specified PHI.
38. Adequate residue data are available for cherries and peaches provided supporting storage stability data are submitted and labels are amended to specify a maximum of five applications per season at a maximum rate of 1.05 lb ai/A/application. However, if the registrant intends to support the higher label-specified application rate of 1.6 lb ai/A/application for peaches, a new set of peach field trials must be conducted using the higher application rate.
39. Storage stability data is still needed for this rac.
40. HED No. 17446, DP Barcode D227366, S. Funk, 2/6/97.

Table B (*continued*).

41. Data are required depicting residues of thiophanate-methyl and MBC in/on almonds and almond hulls harvested at maturity following two foliar applications of thiophanate-methyl (WP, WDG or FIC) applied at pink bud and petal fall at 1.4 lb ai/A/application. A minimum of five field tests are required in Region 10. The registrant has submitted residue studies for almonds and these are currently under review (MRID 44498501).
42. Data are required depicting residues of thiophanate-methyl and MBC in/on pecans harvested at maturity following multiple foliar applications of thiophanate-methyl (WP/WDG and FIC) at 0.7 lb ai/A/application at 21-day intervals up to shuck split. A minimum of five field trials should be conducted; two in Region 2 and one each in Regions 4, 6, and 8. At least three of these trials should include side-by-side comparisons of applications of a WP/WDG formulation with the FIC formulation. The registrant has submitted residue studies for pecans and these are currently under review.
43. A review was not available for these submissions which may contain relevant data.
44. The available residue data for wheat forage, hay, and straw are inadequate because of deficiencies in the analytical method. Unacceptable method recoveries were obtained from control samples of forage, hay, and straw fortified with thiophanate-methyl at the reported LOQ, and apparent residues of MBC were detectable in control samples of forage, hay, and straw at levels in excess of the current 0.1 ppm tolerance.  
  
The registrant must modify the analytical method to improve recoveries of thiophanate-methyl and MBC from wheat forage, hay, and straw and either reanalyze the existing residue samples or conduct a new set of field trials for spring wheat.
45. Data are required depicting residues of thiophanate-methyl and MBC in/on both bagged and unbagged whole bananas harvested at the minimum interval following the labeled application(s) of thiophanate-methyl at the maximum use rate. A minimum of five field trials must be conducted. These trials should be distributed proportionally among the countries where this use is allowed, and the number of tests should be split between bagged and unbagged bananas. Alternatively, a single sample of bagged and unbagged bananas could be collected from each field trial. If the use of both WP and FIC formulations is allowed, at least three of the trials should include side-by-side comparisons of applications of these formulations. Although not required for determining the tolerance, residue data on banana pulp may be provided for purposes of dietary risk assessment.
46. Three additional grape field trials (two in Region 10 and one in Region 1) have been required in conjunction with the review of a petition (PP# 5F4550/6H5734) for a tolerance on grapes (CBTS Nos. 16281, 16282, 166602, 16603, 16604, 16611; DP Barcodes D209958, F. Griffith, 2/2/96).
47. Data are required depicting residues of thiophanate-methyl and MBC in/on peanut nutmeats and hay harvested 14 days following the last of multiple foliar applications of thiophanate-methyl (WP/WDG and FIC) at 0.35 lb ai/A/application. A minimum of 12 field trials should be conducted; eight in Region 2, two in Region 6, and one each in Regions 3 and 8. At least nine of these trials should include side-by-side comparison of applications of a WP/WDG formulation with the FIC formulation, and at least one of the trials should be a residue decline study that includes 3 to 5 additional sampling intervals in addition to the specified PHI. The registrant has submitted residue studies for peanuts and these are currently under review (MRID 44515701).
48. HED Nos. 17900 and 17901, DP Barcodes D 234958 and D234476, L. Cheng, 6/27/97.

Table B (*continued*).

49. HED No. 15423, DP Barcode D214295, S. Funk, 6/8/95; and HED Nos. 13726 and 16783, DP Barcodes D203578 and D222474, S. Funk, 3/25/96.
50. The reregistrant has submitted processing studies on peanuts, potatoes, soybeans, and sugar beets. These are currently under review.
51. Provided adequate supporting storage stability data are submitted for the residues of concern in animal commodities, an adequate ruminant feeding study is available to use for reassessing tolerances on cattle, goat, hog, horse, and sheep commodities. Storage stability data for animal commodities have been submitted and are currently under review.
52. DP Barcodes D240264, D249897, D249898, D251551, currently under review by HED.
53. DP Barcode D233633, D. Drew, 11/19/98.
54. DP Barcode D241361, L. Cheng, 9/23/98.
55. As residues of concern (MBC and 2-AB) were detected at > 0.01 ppm in lettuce and wheat from 30- to 365-day plant-back intervals in the confined rotational crop study, limited field rotational crop studies are required. Limited field studies should be conducted at two separate test sites using a representative root and tuber vegetable, leafy vegetable, and small grain crop at each site. In accordance with the guidance provided in OPPTS GLN 860.1900, the rotational crops should be planted at the desired rotational crop interval following the maximum number of applications of thiophanate-methyl at the maximum label rate. Residues of thiophanate-methyl and MBC should be determined in the appropriate RACs from each rotational crop.

## TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of thiophanate-methyl in/on plant and animal RACs are currently expressed in terms of thiophanate-methyl, its oxygen analogue [dimethyl-4,4'-*o*-phenylene bis(allophanate)], and its benzimidazole-containing metabolites, (calculated as thiophanate-methyl) [40 CFR §180.371]. A feed additive tolerance has been established for thiophanate-methyl residues in dried apple pomace at 40 ppm [40 CFR §186.5700].

The HED Metabolism Committee (S. Funk, 3/6/97) has concluded that the residues to be regulated in plant and animal commodities for purposes of tolerance enforcement will consist of thiophanate-methyl and MBC. The tolerance definition listed under 40 CFR §180.371 should be changed to the following:

Tolerances are established for the combined residues of thiophanate-methyl (dimethyl [(1,2-phenylene) bis (iminocarbonothioyl)] bis (carbamate)) and its metabolite methyl 2-benzimidazolyl carbamate (MBC), calculated as thiophanate-methyl, in or on the following raw agricultural commodities:

A summary of the thiophanate-methyl tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

### Tolerances Listed Under 40 CFR §180.371:

All reassessed tolerances must be considered tentative as the adequacy of the available residue data depends upon submission of acceptable storage stability data.

Provided storage stability issues are resolved and the registrant makes the recommended label amendments, sufficient data are available to ascertain the adequacy of the established tolerances for residues in/on the following commodities: apple, cucurbit vegetables, cherry, onions (dry bulb), plums (fresh prunes), potatoes, strawberry, and wheat grain.

Additional residue data are required before existing tolerances for residues in/on almonds, apricots, bananas, dried peas, peanuts, pecans, potatoes, soybeans, sugar beets, and wheat forage, hay, and straw can be reassessed. Residue data are also required on green onions unless the registrant does not intend to support this use. In which case, the label directions should be modified to restrict the use only to bulb onions and garlic.

Residue data are also required on apricots. Although the registrant indicated that a crop group tolerance would be sought for stone fruit, the available plum, cherry, and peach data indicate that a crop group tolerance is not appropriate for stone fruits due to the large differences in the residues resulting from similar applications. Based upon similar applications, maximum residues were 0.38 ppm in/plums and 16.3 ppm in/on cherries.

Individual tolerances for cucumbers, melons, pumpkins, and squash should be revoked and a crop group tolerance for cucurbit vegetables (Crop Group 9: cucumber, gherkin, watermelon, pumpkin, melons, and squash) should be established at 1.0 ppm.

Tolerances for residues in/on bean forage and hay and peanut forage and hulls should be revoked as the Agency no longer considers these commodities to be significant livestock feed items (Table 1 in OPPTS Guideline 860.1000). The tolerance for thiophanate-methyl residues in/on prunes should also be revoked as residues of thiophanate-methyl and MBC did not concentrate in prunes processed from treated plums. In accordance with 40 CFR §180.1 (h), the tolerance for residues in/on peaches covers nectarines. Therefore, the individual tolerance for residues in/on nectarines should be deleted. Since the registrant has cancelled the sugarcane registration, the tolerance for residues in/on sugarcane should be revoked.

The available residue data indicate that tolerances should be lowered on apples (2 ppm), dry bulb onions (0.5 ppm), peaches (3 ppm), and plums (0.5 ppm). The data also indicate that increased tolerances are necessary for cherries (20 ppm) and strawberries (7 ppm).

Provided storage stability issues pertaining to residues in animal commodities are resolved, sufficient data are available to ascertain the adequacy of the established tolerances for residues in cattle, goat, horse, and sheep commodities. Data from the available ruminant feeding study indicates that the 0.15 ppm tolerances for residues in fat, meat, and meat-by-products of cattle, goats, horses, and sheep are adequate. The separate tolerances for residues in liver and kidneys should be revoked, and the 1.0 ppm tolerance for residue in milk should be lowered to 0.15 ppm.

Based upon the calculated maximum theoretical dietary burden for swine (0.09 ppm) and data from the ruminant feeding study, a Category 3 [40 CFR §180.6(a)(3)] situation exists for thiophanate-methyl and MBC residues in hog commodities. Therefore, tolerances for residues in hog commodities should be revoked.

In the poultry feeding studies, residues of TM, MBC, and 5'-OH-MBC were each <0.05 ppm, (<LOQ) at a dosing level equivalent to 21x the calculated maximum theoretical dietary burden. These data indicate that there is no reasonable expectation of residues [40 CFR §180.6(a)(3)] in poultry commodities. The currently established tolerances for residues of TM in poultry commodities should be revoked.

#### Tolerances Listed Under 40 CFR §186.5700:

Sufficient data are available to ascertain the adequacy of the established 40.0 ppm feed additive tolerance for residues in dried apple pomace. As the Agency no longer considers dried apple pomace to be a significant livestock feed item, the tolerance for residues in dried apple pomace is no longer necessary and should be revoked.

Table C. Tolerance Reassessment Summary for Thiophanate-methyl.

Commodity	Current Tolerance (ppm)	Tolerance <sup>a</sup> Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
<b>Tolerances listed under 40 CFR §180.371:</b>			
Almonds	0.2	TBD <sup>b</sup>	Residue data are under review.
Almond, hulls	1.0	TBD	Residue data are under review.
Apples	7.0	2.0	The available residue data indicate that the tolerance can be reduced. <i>Apples</i>
Apricots	15.0	TBD	Residue data are required. <i>Apricots</i>
Bananas	2.0	TBD	Additional field trials are required.
Bananas, pulp	0.2	TBD	Additional field trials are required.
Beans, dry	2.0	0.2	The available data indicate the tolerance can be lowered. <i>Bean, seeds</i>
Beans, forage	50.0	Revoke	With the exception of cowpea forage and hay, bean forage and hay are no longer considered significant livestock feed items.
Beans, hay	50.0		
Beans, snap	2.0	2.0	The available lima and snap bean residue data support a 2.0 ppm tolerance for residues in/on <i>beans, succulent</i> .
Beets, sugar, root	0.2	TBD	Residue data are required.
Beets, sugar, tops	15.0		
Cattle, fat	0.1 (N)	0.15	The available ruminant feeding study indicates that tolerances of 0.15 ppm are appropriate and that a single tolerance for residues in <i>cattle, mbyp</i> should be established.
Cattle, kidney	0.2	Revoke	
Cattle, liver	2.5	Revoke	
Cattle, mbyp (exc. kidney & liver)	0.1 (N)	0.15	
Cattle, meat	0.1 (N)	0.15	
Celery	3.0	Revoke	Celery registration was cancelled by the registrant
Cherries	15.0	20.0	The available residue data indicate that the tolerance should be increased. <i>Cherries</i>
Cucumbers	1.0	Revoke	Individual tolerances for cucumbers, melons, pumpkins, and squash should be revoked and a crop group tolerance for cucurbit vegetables (Crop Group 9: cucumber, gherkin, watermelon, pumpkin, melons, and squash) should be established at 1.0 ppm.
Eggs	0.1 (N)	Revoke	40 CFR § 180.6 (a) (3)

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance <sup>a</sup> Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Goat, fat	0.1 (N)	0.15	The available ruminant feeding study indicates that tolerances of 0.15 ppm are appropriate and that a single tolerance for residues in <i>goat, mbyp</i> should be established.
Goat, kidney	0.2	Revoke	
Goat, liver	2.5	Revoke	
Goat, mbyp (exc. kidney & liver)	0.1 (N)	0.15	
Goat, meat	0.1 (N)	0.15	
Hogs, fat	0.1 (N)	Revoke	Based upon the maximum theoretical dietary burden for swine and data from the ruminant feeding study, a Category 3 [40 CFR §180.6(a)3] situation exists for thiophanate-methyl residues in hog commodities.
Hogs, liver	1.0		
Hogs, mbyp (exc. liver)	0.1 (N)		
Hogs, meat	0.1 (N)		
Horses, fat	0.1 (N)	0.15	The available ruminant feeding study indicates that tolerances of 0.15 ppm are appropriate and that a single tolerance for residues in <i>horse, mpbyp</i> should be established.
Horses, liver	1.0	Revoke	
Horses, mbyp (exc. liver)	0.1 (N)	0.15	
Horses, meat	0.1 (N)	0.15	
Melons	1.0	Revoke	Individual tolerances for cucumbers, melons, pumpkins, and squash should be revoked and a crop group tolerance for cucurbit vegetables (Crop Group 9: cucumber, gherkin, watermelon, pumpkin, melons,and squash) should be established at 1.0 ppm.
Milk	1.0	0.15	Data from the ruminant feeding study indicates that the tolerance can be lowered.
Nectarines	15.0	Delete	In accordance with 40 CFR §180.1 (h) residues in/on nectarines are covered by the tolerance for residues in/on <i>peaches</i> .
Onions, dry	3.0	0.5	The available data indicate that the tolerance can be lowered. <i>Onions, dry bulb</i>
Onions, green	3.0	TBD	Residue data under review.
Peaches	15.0	3.0	Residue data indicate that the tolerance can be lowered provided the registrant amends the use rate. <i>Peaches</i>
Peanuts	0.2 (N)	TBD	Residue data under review.
Peanuts, forage	15.0	Revoke	Commodity is no longer considered a significant livestock feed item.

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance <sup>a</sup> Reassessment (ppm)	Comment/Correct Commodity Definition
Peanuts, hay	15.0	TBD	Residue data under review.
Peanuts, hulls	2.0	Revoke	Commodity is no longer considered a significant livestock feed item.
Pecans	0.2	TBD	Residue data under review.
Plums	15.0	0.5	Available data indicates that the tolerance can be lowered. <i>Plums, (fresh prunes)</i>
Potatoes (seed treatment)	0.05	0.1	
Poultry, fat	0.1 (N)	Revoke	40 CFR § 180.6 (a)(3)
Poultry, liver	0.2 (N)		
Poultry, mbyp (exc. liver)	0.1 (N)		
Poultry, meat	0.1 (N)		
Prunes	15.0	Revoke	The tolerance for residues in/on plums covers residues in prunes as residues do not concentrate in prunes processed from treated plums.
Pumpkins	1.0	Revoke	Individual tolerances for cucumbers, melons, pumpkins, and squash should be revoked and a crop group tolerance for cucurbit vegetables (Crop Group 9: cucumber, gherkin, watermelon, pumpkin, melons, and squash) should be established at 1.0 ppm.
Sheep, fat	0.1 (N)	0.15	The available ruminant feeding study indicates that tolerances of 0.15 ppm are appropriate and that a single tolerance for residues in <i>sheep, mpbyp</i> should be established.
Sheep, kidney	0.2	Revoke	
Sheep, liver	2.5	Revoke	
Sheep, mbyp (exc. kidney & liver)	0.1 (N)	0.15	
Sheep, meat	0.1 (N)	0.15	
Soybeans	0.2	TBD	Residue data under review.
Squash	1.0	Revoke	Individual tolerances for cucumbers, melons, pumpkins, and squash should be revoked and a crop group tolerance for cucurbit vegetables (Crop Group 9: cucumber, gherkin, watermelon, pumpkin, melons, and squash) should be established at 1.0 ppm.
Strawberries	5.0	7.0	Residue data indicate that the tolerance should be increased.



Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance <sup>a</sup> Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Sugarcane (seed piece treat Pre-H)	0.1 (N)	Revoke	Sugarcane registration was cancelled by the registrant.
Wheat, grain	0.05	0.05	
Wheat, hay	0.1	TBD	Additional data are required, available data indicates that tolerance will need to be increased.
Wheat, straw	0.1		
Feed Additive Tolerances listed under 40 CFR §186.5700 :			
Apple, pomace, dried	40.0	Revoke	Commodity is no longer considered a significant livestock feed item.
Tolerances to be established under 40 CFR §180.371			
Cucurbit Vegetables (cucumber, gherkin, watermelon, pumpkin, melons, squash)	–	1.0	

<sup>a</sup> Reassessed tolerances are tentative pending submission of supporting storage stability data.

<sup>b</sup> TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

## CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for thiophanate-methyl residues in/on various plant and animal commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex MRLs for thiophanate-methyl are currently expressed as carbendazim (MBC). Once all MRLs for carbendazim (MBC) reach step 8, the CCPR will recommend the deletion of MRLs listed separately for thiophanate-methyl, and the MRLs for carbendazim will cover residues resulting from the use of thiophanate-methyl. The Codex MRL residue definition and the U.S. tolerance definition are currently incompatible and will remain incompatible even after the U.S. tolerance definition is revised, as the revised tolerance definition will include both thiophanate-methyl and MBC.

A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table D.

Table D. Codex MRLs for thiophanate-methyl and applicable U.S. tolerances.

Table D (continued).

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Apple	5 (Po) <sup>a</sup>	CXL	2.0	U.S. data reflect only a pre-harvest use.
Banana	1	CXL	TBD	Residue data are required for reassess U.S. tolerance
Broad bean (green pods/immature seeds)	2	CXL	2.0	
Carrot	5	CXL	None	Not registered for this use in the U.S.
Celery	20 (Po)	CXL	Revoke	Registration cancelled by the registrant
Cereal grains	0.1 (*) <sup>b</sup>	CXL	0.05 (wheat)	Residue data reflecting the U.S. use pattern support a 0.05 ppm tolerance
Cherries	10	CXL	20.0	Residue data reflecting the U.S. use pattern support a 20 ppm tolerance
Chicken fat	0.1 (*)	CXL	--	40 CFR §180.6 (a)(3)
Chicken meat	0.1 (*)	CXL	--	40 CFR §180.6 (a)(3)
Citrus fruits	10 (Po)	CXL	None	Not registered for this use in the U.S.
Common bean (pods and /immature seeds)	2.0	CXL	2.0	
Cucumber	0.5	CXL	1.0	Crop group tolerance will be established.
Currant, Black	5	CXL	None	Not registered for this use in the U.S.
Gherkin	2	CXL	1.0	Crop group tolerance will be established.
Gooseberry	5	CXL	None	Not registered for this use in the U.S.
Grapes	10	CXL	None	Not registered for this use in the U.S.
Lettuce, Head	5	CXL	None	Not registered for this use in the U.S.
Mushrooms	1	CXL	None	Not registered for this use in the U.S.
Onion, Bulb	0.1 (*)	CXL	0.5	Residue data reflecting the U.S. use pattern support a 0.5 ppm tolerance
Peach	10 (Po)	CXL	3.0	U.S. data reflect only a pre-harvest use.
Pear	5 (Po)	CXL	None	
Plums (including prunes)	2	CXL	0.5	Residue data reflecting the U.S. use pattern support a 0.5 ppm tolerance
Raspberries, Red, Black	5	CXL	None	Not registered for this use in the U.S.
Strawberry	5	CXL	7.0	Residue data reflecting the U.S. use pattern support a 7.0 ppm tolerance
Sugar beet	0.1 (*)	CXL	TBD	Residue data are required for reassess U.S. tolerance

Table D (continued).

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Sugar beet leaves or tops	5	CXL	TBD	Residue data are required for reassess U.S. tolerance
Tomato	5	CXL	None	Not registered for this use in the U.S.

<sup>a</sup> The (Po) following the MRL indicates that the MRL reflects a postharvest use.

<sup>b</sup> An asterisk (\*) signifies that the MRL was established at or about the limit of detection.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

HED No: 9865  
DP Barcode: D178252  
Subject: Thiophanate-methyl. Nature of the Residue in Wheat.  
From: S. Funk, HED  
To: B. Crompton, SRRD  
Dated: 7/2/92  
MRID(s) 42298103

HED No: 10682  
DP Barcode: D183172  
Subject: Thiophanate-methyl. Registrant's Response to Review of Nature of the Residue in Wheat and Plan for Remaining Metabolism Studies for 171-4(a).  
From: S. Funk, HED  
To: M. Collantes, SRRD  
Dated: 10/16/92  
MRID(s) None

HED No: 10627  
DP Barcode: D182853  
Subject: Thiophanate-methyl. Nature of the Residue in Animals (171-4(b)).  
From: S. Funk, HED  
To: M. Collantes, SRRD  
Dated: 11/10/92  
MRID(s) 42472101 and 42472102

HED No. 10853  
DP Barcode: D184518  
Subject: Thiophanate-methyl. Supplement to Nature of the Residue in Wheat Metabolism Study for 171-4(a).  
From: S. Funk, HED  
To: M. Collantes, SRRD  
Dated: 12/3/92  
MRID(s) 42533801

HED No: 10788  
DP Barcode: D183907  
Subject: Thiophanate-methyl. Nature of the Residue in Lima Beans. Nature of the Residue in Sugar Beets.  
From: S. Funk, HED  
To: M. Collantes, SRRD  
Dated: 12/18/92  
MRID(s) 42513701 and 42492501

HED No: 11517  
DP Barcode: D189012  
Subject: Thiophanate-methyl. Nature of the Residue in Ruminants (171-4(b)).  
From: S. Funk, HED  
To: M. Collantes, SRRD  
Dated: 3/11/93  
MRID(s) None

HED No: 11385  
DP Barcode: D188134  
Subject: Thiophanate-methyl. Nature of the Residue in Ruminants (171-4(b)).  
From: S. Funk, HED  
To: B. Sidwell, SRRD  
Dated: 4/13/93  
MRID(s) 42658301

HED No: 11599  
DP Barcode: D189303  
Subject: Thiophanate-methyl: Analytical Enforcement Method for Crop and Processed Commodity Residues.  
From: S. Funk  
To: B. Sidwell/M. Collantes, SRRD  
Dated: 8/16/93  
MRID(s) 42683601

HED No: 12395  
DP Barcode: D194267  
Subject: Reregistration of Thiophanate-methyl. Interim Report on the Determination of Unknown Metabolites from the Nature of the Residue in Ruminants Study.  
From: S. Funk, HED  
To: B. Sidwell, SRRD  
Dated: 10/15/93  
MRID(s) 42874101

HED No: 12811  
DP Barcode: D196593  
Subject: Reregistration of Thiophanate-methyl. Report on the Determination of Unknown Metabolites from the Nature of the Residue in Ruminants Study.  
From: S. Funk, HED  
To: B. Sidwell, SRRD  
Dated: 12/7/93  
MRID(s) 42995001

HED No: 13939

DP Barcode: D199837  
Subject: Reregistration of Thiophanate-methyl. Report on the Determination of Unknown Liver Metabolites from the Nature of the Residue in Ruminants. Study Supplements 1 and 2.  
From: S. Funk, HED  
To: B. Sidwell, SRRD  
Dated: 3/10/94  
MRID(s) 43095701, 43137801, and 43137802

HED No: 11492  
DP Barcode: D188822  
Subject: Thiophanate-methyl. Confined Rotational Crop Study.  
From: S. Funk, HED  
To: B. Sidwell/M. Collantes, SRRD  
Dated: 3/10/94  
MRID(s) 42670501

HED No: 15504 and 15554  
DP Barcode: D214622 and D215191  
Subject: Thiophanate-methyl. Proposed Analytical Enforcement Method for Plant Commodities.  
From: S. Funk, HED  
To: K. Davis/S. Bacchus, SRRD  
Dated: 6/8/95  
MRID(s) 43521901 and 43624801

HED No: 15423  
DP Barcode: D214295  
Subject: Magnitude of the Residue in Processed Apple Commodities (GLN 171-4(1)).  
From: S. Funk, HED  
To: K. Davis, SRRD  
Dated: 6/8/95  
MRID(s) 43591901

HED No: 15472  
DP Barcode: D214690  
Subject: Magnitude of the Residue in Apples.  
From: S. Funk, HED  
To: K. Davis, SRRD  
Dated: 6/8/95  
MRID(s) 43516301

CBTS Nos: 16281, 16282, 16602, 16603, 16604, and 16611  
DP Barcode: D219884, D219890, D221502, D221593, and D221595,

Subject: PP# 5F4550/6H55734 - Thiophanate methyl (Topsin) on Pears and Grapes.  
Review of Analytical Method and Residue Data.

From: F. Griffith, HED

To: M. Metzger, HED

Dated: 2/2/96

MRID(s) 43750901, 43750902, 43521901, and 43701701

HED No: 16783 and 13726

DP Barcode: D222474 and D203578

Subject: Elf-Atochem North American, Inc. Response to the Review of Magnitude of the  
Residue in Apples and in Processed Apple Commodities (GLN 171-4 (k,1)).  
Status of Residue Chemistry Requirements.

From: S. Funk, HED

To: K. Depukat, SRRD

Dated: 3/25/96

MRID(s) None

HED No: 17318

DP Barcode: D226578

Subject: Thiophanate-methyl. Response of Elf Atochem to Review of the Confined  
Rotational Crop Study.

From: S. Funk, HED

To: P. Deschamp, HED

Dated: 8/20/96

MRID(s) None

HED No: 14263

DP Barcode: D206837

Subject: Thiophanate-methyl. Nature of the Residue in/on Apples.

From: S. Funk, HED

To: P. Deschamp, HED

Dated: 9/18/96

MRID(s) 43337801

HED No: 17578

DP Barcode: D229851

Subject: Thiophanate-methyl. Nature of the Residue in/on Sugar Beets and Lima Beans,  
Supplemental Information (171-4(a); OPPTS 860.1300).

From: S. Funk, HED

To: P. Deschamp, HED

Dated: 11/14/96

MRID(s) 44103201 and 44103202

HED No: None

DP Barcode: None  
Subject: Thiophanate-methyl. Issues to be Presented to the HED Metabolism Committee on 12/17/96.  
From: S. Funk, HED  
To: HED Metabolism Committee  
Dated: 12/11/96  
MRID(s) None

HED No: 17446  
DP Barcode: D227366  
Subject: Thiophanate-methyl. Magnitude of the Residue in/on Plums.  
From: S. Funk, HED  
To: P. Deschamp, HED  
Dated: 2/6/97  
MRID(s) 44036301

HED No: 17713  
DP Barcode: D232388  
Subject: Thiophanate-methyl. Protocol for Plant Commodity Storage Stability Studies.  
From: S. Funk, HED  
To: P. Deschamp  
Dated: 2/26/97  
MRID(s) None

HED No: None  
DP Barcode: None  
Subject: Thiophanate-methyl. Metabolism in Plants and Animals. The Metabolism Committee Meeting Held on January 21, 1997.  
From: S. Funk, HED  
To: HED Metabolism Committee  
Dated: 3/6/97  
MRID(s) None



HED Nos: 16891, 17047, 17411, 17414, 17532, 17561, 17644, 17680, and 17681  
DP Barcode: D222642, D224324, D229238, D229962, D231210, D231690, D231851, D232400, and D232401  
Subject: Thiophanate-methyl. Magnitude of the Residue in Beans (dry and snap), Cherries, Onions, Peaches, and Wheat; Residues in Processed Commodities of Apples, Plums, and Wheat; and Storage Stability Data for MBC in Representative Plant Commodities.  
From: S. Funk, HED  
To: Karen Whitby  
Dated: 7/7/97  
MRID(s) 44083801, 44083802, 44148201, 44161001, 44162001, 44182401, 44184301, 43887101, 44106901, 43948201, and 44073301.

HED Nos: 17900 and 17901  
DP Barcode: D234476 and D234958  
Subject: Thiophanate-methyl. Magnitude of the Residue in Strawberries and Magnitude of the Residue in Milk, Meat, and Meat-by-Products.  
From: S. Funk, HED  
To: Karen Whitby  
Dated: 8/5/97  
MRID(s) 44228801 and 442232401.

HED Nos: n/a  
DP Barcode: D240265  
Subject: Residues of Thiophanate-methyl and its Metabolites in Eggs and Tissues of Laying Hens.  
From: Sheila Piper  
To: Karen Whitby  
Dated: 2/12/98  
MRID(s) 44287501

HED Nos: n/a  
DP Barcode: D240260, D240263  
Subject: Registrant's Letter of March 18, 1997 and May 2, 1997.  
From: Leung Cheng  
To: Catherine Eiden  
Dated: 2/23/98  
MRID(s) None

HED Nos: n/a  
DP Barcode: D243127, D241362, D241363  
Subject: Magnitude of the Residue of Thiophanate-Methyl in Cucumbers. Interim Storage Stability Data in Winter Wheat Grain, Snap Beans, Cucumbers, Sugar Beets, and Apples.  
From: Sheila Piper  
To: Pauline Wagner  
Dated: 6/5/98  
MRID(s) 44471401, 44401801, 44401802, 44401803, 44401804, 44400001

HED Nos: n/a  
DP Barcode: D243122  
Subject: Magnitude of the Residue of Thiophante-methyl in Summer Squash.  
From: Sheila Piper  
To: Pauline Wagner  
Dated: 6/23/98  
MRID(s) 44467901

HED Nos: n/a  
DP Barcode: D243124  
Subject: Magnitude of the Residue of Thiophanate-methyl in Watermelons and Potatoes.  
From: Sheila Piper  
To: Pauline Wagner  
Dated: 6/29/98  
MRID(s) 44468201, 44468202

HED Nos: n/a  
DP Barcode: D245800  
Subject: Rotational Crop Protocol.  
From: Leung Cheng  
To: Pauline Wagner  
Dated: 7/7/98  
MRID(s) None

HED Nos: n/a  
DP Barcode: D245784, D245781, D245788, D245791  
Subject: Interim Storage Stability Data in Winter Wheat Grain, Snap Beans, Cucumbers and Sugar Beets.  
From: Mohsen Sahafeyan  
To: Pauline Wagner  
Dated: 7/22/98  
MRID(s) 44533302, 44533301, 44533303, 44533304

HED Nos: n/a  
DP Barcode: D241361  
Subject: Nature of the Residue in Carrot - 860.1850: Confined Accumulation in Rotational Crops, and Frozen Storage Stability Data.  
From: Leung Cheng  
To: Jess Rowland  
Dated: 9/23/98  
MRID(s) 44415901

HED Nos: n/a  
DP Barcode: D233633  
Subject: Registrant's Response to Residue Chemistry Data Requirements, Storage Stability of <sup>14</sup>C Residues in Confined Rotational Crop Studies.  
From: Danette Drew  
To: John Newland  
Dated: 11/19/98  
MRID(s) 44216201

HED Nos: n/a  
DP Barcode: D241999, D243120  
Subject: Notification of Cancellation of Use on Celerey.  
From: Leung Cheng  
To: Debbie Smegal  
Dated: 2/4/99  
MRID(s) None

HED Nos: n/a  
DP Barcode: D244416  
Subject: Storage Stability Data for Strawberry and Ruminant Feeding Study.  
From: Leung Cheng  
To: Debbie Smegal  
Dated: 2/4/99  
MRID(s) None

HED Nos: n/a  
DP Barcode: D225681  
Subject: Eforcement Method for Plant Commodities.  
From: Leung Cheng  
To: Debbie Smegal  
Dated: 2/8/99  
MRID(s) 43986601

HED Nos: n/a  
DP Barcode: D262958  
Subject: Anticipated Residues, Acute and Chronic Dietary Risk Assessments for Thiophanate-methyl (TM) and its Metabolites Methyl 2-benzimidazolyl carbamate (MBC) and 2-Aminobenzamidazole (2-AB).  
From: Sheila Piper  
To: John Leahy and Deborah Smegal  
Dated: 2/8/00  
MRID(s) None

HED Nos: n/a  
DP Barcode: D265906  
Subject: Revised Chronic Carcinogenic Dietary Risk Assessments for Thiophanate-methyl (TM) and its Metabolites Methyl 2-Benzimidazolyl Carbamate (MBC) and 2-Aminobenzamidazole (2-AB).  
From: Sheila Piper  
To: John Leahy and Deborah Smegal  
Dated: 5/10/00  
MRID(s) None

HED Nos: n/a  
DP Barcode: D230335  
Subject: HED Product Chemistry and Residue Chemistry Chapters of the RED.  
From: José J. Morales  
To: Deborah Smegal and John Leahy  
Dated: 6/16/00  
MRID(s) None

HED Nos: n/a  
DP Barcode: D271921  
Subject: Revised Anticipated Residues, Acute and Chronic Dietary Risk Assessments for Thiophanate-methyl (TM) and its Metabolites Methyl 2-Benzimidazolyl Carbamate (MBC) and 2-Amine-1-H-benzimidazole (2-AB).  
From: Sheila Piper  
To: Deanna Scher and Deborah Smegal  
Dated: 2/1/01  
MRID(s) None

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Bibliographic citations include only MRIDs containing data which fulfill data requirements.

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